Application No.: 10/539,954 Docket No.: 13195-00006-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Oliver Schmitz et al.

Application No.: 10/539,954

Confirmation No.: 8865

Filed: June 17, 2005

Art Unit: 1652

For: METHOD FOR PRODUCING AMINO ACIDS

Examiner: Chowdhury, Iqbal H.

RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the restriction requirement set forth in the Office Action mailed November 3, 2006, Applicants provisionally elect Group I (claims 1-2 and 4-17) and the sequence of SEQ ID NO: 2, with traverse. Reconsideration and withdrawal of the restriction requirement is strongly urged for the following reasons.

The Claimed Inventions Share a Special Technical Feature

Because this application is a national stage filing pursuant to 35 U.S.C. § 371, unity of invention under PCT Rule 13.1 and 13.2 is the applicable standard. Unity of invention is fulfilled "when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical feature. The expression 'special technical feature' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (PCT Rule 13.2).

The Examiner argues that the inventions of Groups I-VI do not relate to a "special technical feature" which defines a contribution over the prior art, citing Monschau et al. (Appl. Environ. Microbiol., 1998, 64(11): 4283-4290) and GenBank Accession No. AAL52676. Applicants respectfully disagree that the inventions of the present application do not make a contribution over the references cited by the Examiner.

As stated in the specification, the general inventive concept of the present application relates to the use of transgenic organisms whose amino acid biosynthesis pathway is modified for the preparation of methionine, homoserine and lysine, and to the transgenic organisms themselves. Preferably, the amino acid biosynthesis pathway is modified by introducing a nucleic acid which increases threonine degradation, lysine degradation, or both threonine and lysine degradation in the transgenic organism.

The reference cited by the Examiner, Monschau et al., teaches the preparation of riboflavin (vitamin B2) in *Ashbya gossypii*, a filamentous hemiascomycete, by overexpressing an *Ashbya* threonine aldolase. The GenBank Accession No. cited, AAL52676, discloses lysine decarboxylase from *Brucella melitensis*. Neither reference teaches the production of genetically modified organisms for the preparation of amino acids, let alone the specific amino acids recited in the claims of methionine, homoserine and lysine. Particularly, none of the references teaches that an increase of *Saccharomyces cerevisiae* (yeast) threonine aldolase (SEQ ID NO: 2) leads to an increased production of methionine, homoserine and lysine.

Accordingly, the inventive concept of modifying the amino acid biosynthesis pathway by increasing the expression of a nucleic acid that increases threonine degradation, lysine degraddation, or both threonine and lysine degradation in the transgenic organism, particularly the yeast threonine aldolase (SEQ ID NO: 2), is the common technical feature shared by all of the claims of Restriction Groups I to VI. For instance, the polypeptides of Restriction Group VI are produced in the method of Restriction Groups I and II, which leads to the production of the transgenic organism included in Restriction Groups III and IV. Furthermore, overexpression of a nucleic acid construct comprising a nucleic acid that encodes for a protein which increases threonine, or lysine, or threonine and lysine degradation, preferably the yeast threonine aldolase (SEQ ID NO: 2), as stated in claims of Restriction Groups III and IV, leads to an increased amino acid production in transgenic organisms according to the invention as disclosed in claims of Restriction Groups I and II. According to Section 131(ii) of the WIPO Applicants Guide, a process and an apparatus specifically designed for use in that process are considered as having unity of invention. A vector as claimed in claims of Restriction Groups III and IV is specifically designed for carrying out the methods of the present invention. Therefore, these claims are to be considered together. Additionally, the transgenic organism of Restriction Groups III and IV is used in the process for producing animal food, cosmetics or pharmaceutical according to

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Restriction Group V. Therefore, these claims should be considered together as having unity of invention, and could be examined together with minimal burden.

Furthermore, Applicants respectfully submit that the restriction requirement should be withdrawn even under U.S. restriction practice. As stated in § 803 of the M.P.E.P. "[i]f the search and examination of the entire application can be made without serious burden, the examiner <u>must</u> examine it on the merits, even though it includes claims to independent or distinct inventions." (M.P.E.P. § 803, emphasis added). Because the same art relevant to a threonine-, or lysine-, or threonine and lysine degrading protein would also be relevant to a method of using it in modifying the production of amino acid in genetically modified organisms, there would be no undue burden on the Examiner to search and examine these Groups together, since the subject matter of the various groups is so closely linked and would be classified together for search.

In the alternative, Applicants respectfully request that the claims in Restriction Groups I, III, V and VI should be examined together for the same reasons as explained above.

The Examiner further requires Applicants to elect a single species of threonine-, or lysine-, or threonine and lysine degrading proteins. Applicants disagree with this requirement and request reconsideration and withdrawal. The sequences are related to each other by sharing a common specific enzymatic activity of threonine aldolase or lysine decarboxylase. For example, sequences of SEQ ID NOs: 2, 3, 4, 5, 6, 7, 8, 9, 10, 14 and 16 are all threonine aldolase, and sequences of SEQ ID NOs: 12, 18, 20, 22, 24 and 26 are all lysine decarboxylase. For these reasons, Applicants respectfully request that the requirement for restriction to one sequence be reconsidered and removed entirely.

Alternatively, restriction to one the groups of sequences having the same enzymatic activity, i.e., threonine aldolase or lysine decarboxylase, is requested. The sequences in each of these groups share a common specific enzymatic activity, and thus, could be examined together with minimal burden.

CONCLUSION

For at least the above reasons, Applicants respectfully request that the restriction requirement be reconsidered and withdrawn.

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This response is filed within one-month period for response from the mailing of the Office Communication, to and including December 3, 2006. No fee is believed due. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 13195-00006-US from which the undersigned is authorized to draw.

Respectfully submitted,

Ву____

Hui-Ju Wu, Ph.D.

Registration No.: 57,209

CONNOLLY BOVE LODGE & HUTZ LLP

1007 North Orange Street

P.O. Box 2207

Wilmington, Delaware 19899

(302) 658-9141

(302) 658-5614 (Fax)

Agent for Applicants

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